K080844

Page 1 of (2)

510(k) Summary of Safety and Effectiveness
Gyrus ACMI Inc.
Gyrus ACMI G3 Generator and Accessories - Dissector Plasma Knife

AUG 1 3 2009

General Information

Manufacturer:	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta Regulatory Affairs Tel. #: 508-804-2752 Fax #: 508-804-2624
Date Prepared:	March 18, 2008
Device Description	Classification Name: Electrosurgical cutting and coagulation devices and accessories (21CFR 878.4400, Class II)
Trade Name:	Gyrus ACMI G3 Generator and Accessories - Dissector Plasma Knife
Generic/Common Name:	Electrosurgical cutting and coagulation devices and accessories

Predicate Devices

Gyrus ACMI G3 Generator and Accessories - Dissector Plasma Knife K041285

Intended Uses

The Bipolar Generator section of the G3 RF Workstation and accessories are indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (Head and Neck) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal / Laryngeal indications including Tracheal Procedures, Laryngeal
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Tonsillectomy
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring
- Uvulopalatopharyngoplasty (UPPP)
- Parotidectomy

Polypectomy, and Laryngeal Lesion Debulking · Neck Mass
· Neck Dissection (Radical and Modified Neck Dissection)

The Gyrus ACMI Dissector Plasma Knife is indicated for resection and coagulation of soft tissue and hemostasis of blood vessels in head and neck surgery including Neck Dissection (Radical and Modified Neck Dissection), Tonsillectomy, Parotidectomy and UPPP when used with the bipolar generator section of the G3 Workstation.

Product Description

The Gyrus ACMI® G3 Generator is an electrosurgical generator containing five key components:
A dual output electrosurgical generator;
Monopolar output side
Bipolar output side
Disposables;
Monopolar electrodes (TCRF)
- Bipolar PlasmaCision Electrodes

Connector Cables
Monopolar return pad; and
Footswitch.

The Gyrus G3 System Generator has two principal modes of operation dependant on which type of electrode is attached - The monopolar mode has controls for maximum temperature and energy delivered. The unit has readouts for total energy delivered, impedance, temperature for two thermocouples and time of energy delivery. - The bipolar mode has controls for output waveform type and power. The unit has readouts for set power and waveform. Connectors on the front panel include the monopolar connector for active electrode and dispersive electrode and separate dual bipolar connectors for PlasmaCision electrodes and bipolar instruments. The device is operated by a foot pedal, connected on the back panel.

The Dissector Plasma Knife is a single use disposable bipolar instrument designed for use with the G3 generator within an ambient air environment. The instrument incorporates a suction channel, which allows for suction of fluids and gases during operative procedures when connected to an appropriate suction facility.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI® G3 Generator and Accessories - Dissector Plasma Knife are composed of the same materials and identical features of those of the predicate. There are no changes to the design of the generator or instrument pursuant to this submission. Therefore In summary, the Gyrus ACMI is substantially equivalent to the predicate device and presents no new questions of safety or efficacy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Gyrus ACMI, Inc.
% Ms. Lorraine Calzetta
Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772-2104

AUG 13 2009

Re: K080844
Trade/Device Name: Gyrus ACMI® G3 Generator and Accessories – Dissector Plasma Knife
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 12, 2009
Received: July 23, 2009

Dear Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI® G3 Generator and Accessories - Dissector Plasma Knife

510(k) Number: K080844

Indications for use:

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Prescription Use: __x __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K080844